

REMARKS

Entry of the foregoing, reexamination, and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.111 and § 1.112, are respectfully requested.

I. Amendments to the Claims

By the foregoing amendment, claims 1, 31, 32, 39, 48, 50, 53-56, 67, 77, 78, 82, 92, 104, and 105 have been amended. In particular, claim 1 has been amended to recite the limitations of claim 30. Corresponding amendments have also been made to withdrawn claims 39, 48, 50, 53-56, 67, 82, and 92. Further, claims 31 and 32 have been amended to clarify that the polymer comprises " at least one cysteine group." In addition, because withdrawn claims 51 and 104 also recite cysteine groups, similar amendments have been made to claims 51 and 104. New claim 110, reciting a subset of the polymers recited in claim 1, has been added. Support for the amendments may be found throughout the specification and claims as filed. Thus, no new matter has been added.

In addition, claims 30, 74, and 109 have been canceled without prejudice or disclaimer to the subject matter recited therein. Applicants reserve the right to file at least one continuation and/or divisional application directed to any canceled subject matter.

Entry of the foregoing amendments of the above-identified application are respectfully requested.

II. Response to Rejections Under 35 U.S.C. § 112, Second Paragraph

At page 3 of the Office Action, claim 31 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Examiner has stated that recitation of "the thiol groups are cysteine groups" renders the claim ambiguous. This rejection is respectfully traversed.

To expedite prosecution in the present application and not to acquiesce to the Examiner's rejection, claim 31, as noted above, has been amended by replacing the phrase "wherein said thiol groups are cysteine groups" with the phrase "wherein said polymer comprises at least one cysteine group."

Accordingly, the pending claims particularly point out and distinctly claim the subject matter of the invention. As such, Applicants respectfully request reconsideration and withdrawal of this rejection.

IV. Response to Claim Rejections Under 35 U.S.C. § 102

A. *Omura et al., U.S. Patent No. 5,064,495*

At pages 4 and 5 of the Office Action, claims 1, 33, and 35-38 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Omura et al., U.S. Patent No. 5,064,495 ("Omura"). This rejection is respectfully traversed.

Again, to expedite prosecution and not to acquiesce to the Examiner's rejection, claim 1 has been amended to recite the limitations of claim 30, and claims 33 and 35-38 depend from claim 1. Because claim 30 is not included in the rejection over Omura, the above-mentioned amendments to claim 1 should be sufficient to overcome this rejection.

Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

B. *Constancis et al., U.S. Patent No. 5,646,239*

At page 5 of the Office Action, claims 1, 30-33, and 35-38 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Constancis et al., U.S. Patent No. 5,646,239 ("Constancis"). This rejection is respectfully traversed.

According to the Examiner, Constancis teaches oligomeric moieties that contain a thiol group. The Examiner has concluded that the Constancis polymers meet all the elemental limitations of the present claims, and thus must also possess the recited total work of adhesion. Further, the Examiner has contended that the Constancis oligomers can be synthetically attached to polysaccharides and mucopolysaccharides including hyaluronic acid, chitosan, and cellulose (citing col. 6, lines 8-15).

As noted above, claim 1 has been amended without prejudice or disclaimer to recite the limitations of claim 30. Thus, applicant's comments below are directed to the as-amended claims.

It is well established that for prior art to be anticipatory, every element of the claimed invention must be disclosed in a single item of prior art in the form literally defined in the claim. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 213 U.S.P.Q. 81, 90 (Fed. Cir. 1986).

Applicants submit that Constancis fails to satisfy this requirement, for at least the following reasons.

In contrast to the present invention, Constancis does not disclose mucoadhesive polymers. The Second Declaration of Dr. Bernkop-Schnürch (originally submitted on August 7, 2003 in the present application), showed that the Constancis polymers were not mucoadhesive and did not exhibit a TWA of at least 120 μ J. For the Examiner's convenience, a copy of the Second Declaration of Dr. Bernkop-Schnürch is submitted herewith as Exhibit A.

As concluded by Dr. Bernkop-Schnürch, the testing evidenced that none of the polymers described by Constancis displayed statistically significant mucoadhesive properties. If an inert and completely not mucoadhesive material was tested, similar results would have been obtained. The results are in good agreement with the generally accepted theory about criteria, which have to be fulfilled by a polymer in order to be mucoadhesive (e.g., G. Hunt, P. Kearney and I. Kellaway, Mucoadhesive polymers in drug delivery systems, in Drug Delivery Systems, Johnson, P. and Lloyd-Jones, J.G. (eds.) Ellis Horwood, New York (1987)). See Second Bernkop-Schnürch Declaration at ¶ 28.

Since the polymers of Constancis do not inherently possess the property of being mucoadhesive and do not exhibit a TWA of 120 μ J, Constancis fails to disclose or even suggest the instantly claimed invention. Constancis in no way discloses or suggests mucoadhesive properties as claimed herein. The Constancis polymers would not adhere to the mucosa with the claimed strength of the mucoadhesive polymers of the instant invention. The Constancis polymers do not even fulfill the minimal criteria to be considered "mucoadhesive." See Second Bernkop-Schnürch Declaration at ¶¶ 27-29.

For at least the reasons set forth above, the present invention is not taught, and thus not anticipated, by Consancis. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

C. *Marchant, U.S. Patent No. 6,514,535*

At page 5 of the Office Action, claims 1, 31-33, and 35-38 have been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Marchant, U.S. Patent No. 6,514,535 ("Marchant"). This rejection is respectfully traversed.

As discussed above, Claim 1 has been amended without prejudice or disclaimer to recite the limitations of claim 30, and claims 31-33 and 35-38 depend ultimately from claim 1. Because claim 30 is not included in the rejection over Marchant, the above-mentioned amendments to claim 1 should be sufficient to overcome this rejection.

Moreover, Marchant allegedly qualifies as prior art under § 102(e) based on a U.S. filing date of May 21, 1999. However, the present application claims priority to Australian Application No. 1828/98, filed on November 4, 1998. A certified copy of the foreign priority document has been forwarded from the International Bureau and receipt has been acknowledged by the Examiner in the Office Action of March 17, 2006. Additionally, enclosed herewith as Exhibit B is a certified English language translation of the priority document. Thus, Marchant is not proper prior art against the present application.

Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

V. Claim Rejections Under 35 U.S.C. § 103

At page 6 and 7 of the Office Action, claims 28-29 have been rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Constancis or Marchant. This rejection is respectfully traversed.

Specifically, the Examiner has stated that although the references fail to teach the concentration of thiol groups as recited in the present claims, absent unexpected results such concentrations would have been obvious.

For at least the reasons set forth above, neither Constancis nor Marchant teach or suggest the mucoadhesive polymers recited in the present claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

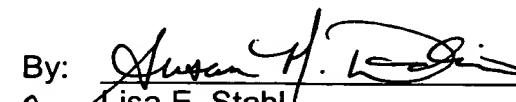

In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 838-6609 so that prosecution of the application may be expedited.

Respectfully submitted,

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